NAA
NATIONAL AQUACULTURE ASSOCIATION
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September 9, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Response to FDA objectives on the FDA Modernization Act of 1997 (Docket No. 98N-0339)

Dear Sir or Madam:

The National Aquaculture Association appreciates the opportunity to respond to questions the FDA has raised regarding the FDA Modernization Act of 1997 (Docket No. 98N-0339).

1. What can FDA do to improve its explanation of the Agency's submission review processes, and make explanations more available to product sponsors and other interested parties?

Answer: The NAA is not aware of any particular problem clients have obtaining or understanding the submission review process. However, the approval process itself is complex, in need of stream lining and requires greater flexibility.

FDA can enhance the approval process by promoting to Congress the document entitled "Proposals to increase the availability of approved animal drugs for minor species and minor uses" that CVM developed with input from minor animal species industries. The NAA has previously provided supporting comment on this document.

It is important to have timely document reviews. FDA needs to provide a timetable for reviews of each type of submission in a document that is circulated to all product sponsors, including compassionate INAD sponsors. FDA then needs to perform reviews in a timely manner. If that means more reviewers, then FDA should go to Congress to ask for more reviewers on behalf of animal health. Reviews of protocols and technical section submissions to NADAs are not timely, especially for minor species such as aquatic species. Many submissions have not been reviewed even 6 to 12 months after they are submitted. Because of the time delay, sponsors do not get feedback on their submissions to determine if they need to change the format, contents, etc. of future submissions and, thus, perpetuate mistakes that continue to increase the time for Agency review.

2. How can the Agency maximize the availability and clarity of information concerning new products?

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Answer: FDA needs to ensure that all information on new products is accessible on its Web Page and placed in a timely manner in the FDA Veterinarian. FDA needs to identify key persons in each industry to provide alerts to, on new products coming through the pipeline to the Federal Register before they are published but after FDA has approved them.

3. How can FDA work with its partners to ensure that products--domestic and foreign--produced and marketed by the regulated industry are of high quality and provide necessary consumer protection; and how can FDA best establish and sustain an effective, timely, and science-based postmarketing surveillance system for reporting, monitoring, evaluating, and correcting problems associated with use/consumption of FDA-regulated products?

Answer: If FDA accepts the tolerances and withdrawal times for the use of certain drugs on animals in other countries, then FDA should allow the use of those same drugs in the U.S. Without this consideration, FDA is creating an uneven playing field for domestic producers. FDA needs to create some kind of interim approval system or conditional approval so that sponsors can meet the data requirements while being allowed to market the very drugs that are allowed by FDA to be used on imported animals. The same withdrawal times and tolerances should apply for foreign and domestic use.

FDA needs to develop a policy for a postmarketing surveillance system that sets priorities for surveillance and compliance for both foreign and domestic production. This suggests that for some compounds, FDA may not do postmarketing surveillance since certain kinds or classes of products are known to be safe for consumption. These decisions should be based on science and the mode of animal culture. A risk management determination, prior to marketing, could guide FDA in developing appropriate surveillance programs. If the Division of Surveillance and Compliance is to do postmarketing surveillance, the Agency needs to ensure that it has sufficient numbers of scientists who are knowledgeable in these areas of expertise. FDA could rely on the domestic industry to assist the Agency in making some of these decisions and help in the review process.

FDA can meet the demands for approval of safe minor species drugs by releasing to Congress the document entitled "Proposals to increase the availability of approved animal drugs for minor species and minor uses" that CVM developed with input from the minor species industries.

4. What approach should FDA use to ensure an appropriate scientific infrastructure with continued access to scientific and technical expertise needed to meet its statutory obligations and strengthen its science-based decision-making process?

Answer: FDA needs to ensure that the best trained scientists and experts in this field are selected for these positions. This may mean improving salaries and changing the selection process. There is too much at stake for our domestic industry to not get the best scientists available in this area of expertise. FDA needs to ensure that CVM's Division of Therapeutic Drugs for Food Animals performs the animal drug evaluation process (pre-approval evaluation) and the Division of Surveillance and Compliance is involved only in the post-approval process. Expert panels composed of scientists outside the agency may also be a valuable tool to ensure an appropriate level of scientific expertise is applied to the process.

FDA can meet the needs for scientific infrastructure for minor species minor use drugs by releasing to Congress the document entitled "Proposals to increase the availability of approved animal drugs for minor species and minor uses" that CVM developed with input from the minor species industries.

5. What do you believe FDA should do to adequately meet the demands that are beginning to burden the application review process, especially for non-user fee products, so that it can meet its statutory obligations to achieve timely product reviews?

Answer: FDA needs to go to Congress and ask that it provide the funds to support the Food Quality Protection Act that they passed. This is another unfunded mandate at a time when Congress has been downsizing FDA budgets. FDA can not meet these requirements without proper funding and staffing of good scientists. The animal health industries would support FDA in this effort. If user fees are required, Congress will kill the animal health industry, especially minor species. FDA can meet the demands for approval of safe minor species drugs by releasing to Congress the document entitled "Proposals to increase the availability of approved animal drugs for minor species and minor uses" that CVM developed with input from the minor species industries. Those provisions that FDA can enact without Congressional approval, the Agency should do immediately.

6. What suggestions do you have for the Agency to eliminate backlogs in the review process?

Answer: FDA needs to request additional funds from Congress to hire more reviewers, utilize outside expert panels and send to Congress the document entitled "Proposals to increase the availability of approved animal drugs for minor species and minor uses" that CVM developed with input from the minor species industries. FDA needs to work more closely with sponsors to ensure that submissions are in the proper format and supply the information that FDA is seeking. One way to do that would be to develop sample submissions as a guide for sponsors. Consideration should be made for drugs that are not human health hazards (based on other long uses, etc.) whereby FDA would not require a whole set of mammalian safety studies. FDA should do more calculations and extrapolations from other uses and the culture systems used. Any drug that has a "Generally Recognized As Safe" ruling for any use should have that status applied to any use. FDA should accept the reviews by regulatory agencies from other countries that have a good review program.

All of these suggestions would decrease the time it takes for reviews and still provide for human food safety.

7. What other objectives related to the Agency's statutory obligations or public expectations, beyond the six objectives, should be included in the FDA plan?

Answer: FDA needs to be proactive regarding funding requirements to get the job done. The Agency needs to get the animal industries involved in the process and keep them informed of its needs.

Please keep us informed of developments regarding the "Proposals to increase the availability of approved animal drugs for minor species and minor uses" and its release to Congress.

Sincerely,

Jesse Chappell

Jesse Chappell, Ph.D.
President

JC:mw

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